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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/417,251	10/13/1999	REBECCA E. CAHOON	BB1085-US-NA	7181

7590 11/30/2001

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WILMINGTON, DE 19898

EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 11/30/2001

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/417,251

Applicant(s)

CAHOON ET AL.

Examiner

Jane Zara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-20,22-30 and 35-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-20,22-30 and 35-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

File

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DETAILED ACTION

This Office action is in response to the communication filed September ^{27,}~~28,~~ 2001, Paper No. 11.

Claims 16-20, 22-30 and 35-38 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

The additional arguments filed September 27, 2001, Paper No. 11, regarding the restriction requirements set forth on March 16, 2001, Paper No. 8, and made final on September 29, 2001, Paper No. 10, are hereby noted. Applicants must amend the pending claims in a manner consistent with the election requirement of a single nucleotide (SEQ ID NO: 9, encoding SEQ ID NO: 10).

An examination on the merits of the pending claims regarding SEQ ID NO: 9 (and polynucleotides encoding the protein disulfide isomerase of SEQ ID NO: 10) has been made as indicated below.

Response to Arguments and Amendments

Withdrawn Rejections

Rejection of claim 21 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention, is withdrawn in light of Applicants' amendments filed September ^{27,} 28, 2001, Paper No. 11.

Rejection of claim 21 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is withdrawn in light of Applicants' amendments filed September 28, 2001, Paper No. 11.

Maintained Rejections

Claims 16-20, 22-30 and 35-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth in the Office action mailed June 29, 2001, Paper No. 10.

Applicant's arguments filed September 27, 2001 have been fully considered but they are not persuasive. Applicants argue that adequate written description has been provided for the full scope claimed because various sequences have been disclosed which encode polypeptides which have assayable, protein disulfide isomerase (PDI) activity, and the assay for determining such activity is well known in the art. Contrary to Applicants' assertions, the disclosure of several sequences encoding functional polypeptides with protein disulfide isomerase activity does not provide adequate description for determining which of the possible myriad of sequences - i.e. any and/or all which are 85% identical to any polynucleotide sequence which could be derived from

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the polypeptide of SEQ ID NO: 10 - are identifiable without further undue experimentation beyond that described in the instant specification. No correlation has been provided between the minimum sequences or minimum domains required to maintain PDI activity, and further whereby such polypeptides encoding these minimum sequences are also free of the prior art. No correlation has been provided between hybridization conditions employed and homology obtained or homology claimed, whereby nucleotides encoding functional PDI polypeptides are obtained and are free of the prior art. Nor has specific guidance for determining the relationship or correlation between such broad homology and hybridization conditions been adequately provided in the instant specification. The employment of a routine assay for determining enzymatic activity is not adequate description for enabling the scope claimed.

Claims 16-20, 22-30 and 35-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons set forth in the Office action mailed June 29, 2001, Paper No. 10.

Applicant's arguments filed September 27, 2001 have been fully considered but they are not persuasive. Applicants argue that it would require routine experimentation to enable the full scope of the claims, drawn to and/or all polynucleotides which are 85% identical to any polynucleotide sequence which could be derived from the polypeptide sequence of SEQ ID NO: 10 because domain homology has been disclosed for PDI's in the instant specification and the

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assay for PDI activity is a routine assay in the art. Contrary to Applicants' assertions, it would require undue experimentation beyond that which has been provided in the instant specification. No correlation has been provided between the minimum sequences or domain constraints required to maintain PDI activity, whereby such polypeptides are free of the prior art. No correlation has been provided between hybridization conditions employed and homology obtained, whereby nucleotides encoding functional PDI polypeptides are obtained and are free of the prior art. Applicants are enabled for the scope drawn to the polynucleotide of SEQ ID NO: 9, encoding the functional polypeptide of SEQ ID NO: 10. Applicants are not entitled to the scope drawn to any polynucleotide of at least 85% identity to any polynucleotide which may encode the polypeptide of SEQ ID NO: 10. It would require undue experimentation beyond which has been taught in the specification to determine which of this myriad of sequence possibilities do indeed encode functional PDI, as well as to determine which conditions must be employed to identify such possibilities.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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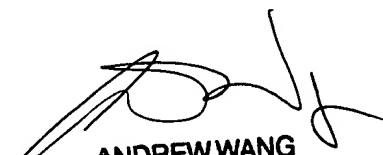
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is (703) 306-5820. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

November 29, 2001



ANDREW WANG
PRIMARY EXAMINER